KANG ZE INDUSTRIAL CO., LTD.
No. 9 Venture Industry Park, Jane Sandbar, Wanjiang Area, Dongguan, Guangdong, China 523063

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K112289
Date:	Aug 5th, 2011
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	KANG ZE INDUSTRIAL CO., LTD. Office Add.: Room 1701, Henan Building, No. 90 Jaffe Road, Wan Chai, HK Factory Add.: No. 9 Venture Industry Park, Jane Sandbar, Wanjiang Area, Dongguan, Guangdong, China 523063
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add.: Room 1706 Yuesha, No. 128 Songle Rd., Songjiang, Shanghai, China 201600 E-mail: doris_d@126.com Tel: 86 21-31261348 Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Disposable Thermometer Covers and Sheaths
Common Name:	Disposable Thermometer Covers and Sheaths
Classification Name:	Clinical electronic thermometer / Clinical mercury thermometer
Regulation Number:	880.2910 / 880.2920
Product Code:	FLL / FLK
Device Class:	Class II
Submission Type:	510(k)
Review Panel:	General Hospital
Indications for use:	The Disposable Thermometer Covers and Sheaths are intended for use as barriers between digital or mercury thermometers and users' rectum or oral cavities to avoid the possible contamination and infection during temperature measuring. These covers and sheaths are non-sterile and intended for single use only.
Device Description:	The Disposable Thermometer Covers and Sheaths, made of PE and EVA, are used for either oral or rectal measurements for digital or mercury thermometers. The products and packaging are non-sterile and are not made with natural rubber latex. The size may vary to accommodate differences in digital and mercury thermometers. The inner packing material is paper, while the outer packing material is carton. Each outer packing contains 100 pieces of covers and sheaths.

3. Substantial Equivalence:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k)

submission.

Predicate 510(k) Numbers:	K983406	K061007
Marketing clearance date:	October 19th, 1998	June 14th, 2006
Product name:	SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury	GOOD MEDY Disposable Thermometer Sheaths
Manufacturer:	Banta Healthcare Products	GOOD MEDY ENTERPRISES LTD
Differences:	The material and packing specification differ from the Predicate Devices of K983406 and K061007.	
Similarities:	Same intended use, non-sterile, and similar testing standards.	
Equivalence conclusion:	The new devices, Disposable Thermometer Covers and Sheaths, are substantially equivalent to the predicate devices: SaniTherm Thermometer Sheaths (K983406) and GOOD MEDY Disposable Thermometer Sheaths (K061007). The devices have same intended use, are non-sterile and latex-free, and passed biocompatibility tests by ISO 10993. Thus the new devices are substantially equivalent to the predicate devices.	

4. Safety and Effectiveness of the device:

The Disposable Thermometer Covers and Sheaths were tested and found to meet the standards of
ISO 10993-5: 1999: Tests for cytotoxicity; In vitro methods,
ISO 10993-10: 2002: Tests for Irritation and Sensitization,
ASTM E1104-98(2003): Standard Specification for Clinical Thermometer Probe Covers and Sheaths,
IEC 62321 Ed.1: Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers), as well as
EPA Method 3546 Microwave extraction.

The conclusion drawn from the bench testing and safety testing is that the device is as safe and effective as the predicate device. Furthermore, the device complies with the recognized standards and performs its intended tasks as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

Kang ZE Industrial Company, Limited
C/O Ms. Doris Dong
Manager
Shanghai CV Technology Company Limited
RM 1706 Yuesha Building
No 128 Songle Road
Songjiang Area, Shanghai

Re: K112289
Trade/Device Name: Disposable Thermometer Covers and Sheaths
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electric Thermometer
Regulatory Class: II
Product Code: FLL, FLK
Dated: November 18, 2011
Received: November 23, 2011

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K 112289

Device Name: Disposable Thermometer Covers and Sheaths

Indications for Use:

The Disposable Thermometer Covers and Sheaths are intended for use as barriers between digital or mercury thermometers and users' rectum or oral cavities to avoid the possible contamination and infection during temperature measuring. These covers and sheaths are non-sterile and intended for single use only.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___√___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Weihung Cui for Richard Chapman
Division Sign-Off
Division of Surgical, Orthopedic,
And Restorative Devices

510(k) Number 112289